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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,223	07/11/2003	Eric K. Mangiardi	000100.0015	4411

37305 7590 11/28/2007

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EXAMINER	
APANIUS, MICHAEL	
ART UNIT	**PAPER NUMBER**
3736	

MAIL DATE	DELIVERY MODE
11/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,223	MANGIARDI ET AL.	
	Examiner	Art Unit	
	Michael Apanius	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-24,37,39-42 and 44-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-24,37,39-42 and 44-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/11/2007 has been entered. The amendments to claims 1, 5, 7, 12, 15, 19, 24, 37 and 41, the addition of new claims 44-57, the replacement drawings sheet, and the amendment to the specification are acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 5, 12 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claims 1, 7 and 37 recite that the inward facing surfaces of the legs are in flush contact with one another from the distal

ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit. Claims 5, 12 and 41 recite that the distal ends of the legs are coupled together as shown in the embodiment of figures 14-18. The original disclosure states, "when the legs are constrained by the exterior conduit 130 they lay substantially flush with respect to one another" (page 9, lines 16-17). However, this statement pertains to the embodiment of figures 1-13 when the distal ends of the legs are not coupled together. Regarding the embodiment of figures 14-18, the original disclosure states, "when the measurement assembly is retracted, the legs are relaxed and reside adjacent one another so that the legs may be retracted within the exterior conduit" (page 10, lines 23-26). However, the original disclosure does not appear to support inward facing surfaces of the legs in the embodiment of figures 14-18 being in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit. Therefore, the subject matter of claims 5, 12 and 41 does not appear to be properly supported by the original disclosure.

4. Claims 46, 49, 50, 53, 54 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 46, 49, 53 and 57 recite, "wherein the distal end of the exterior conduit comprises a lip extending outwardly therefrom." Although the original disclosure appears to support a lip on the

distal end of the exterior conduit, the originally disclosed lip does not appear to be directed outward from the exterior conduit. Therefore, it appears that the subject matter set forth in new claims 46, 49, 50, 53, 54 and 57 is not properly supported by the original disclosure.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 3-8, 10-24, 37 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain (US 5,919,147) in view of Colvin et al. (US 5,010,892), Haddock et al. (US 6,712,771) and Doi (US 6,033,359).

7. Jain teaches a body lumen measuring device for measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis. The device (10) includes an exterior conduit (22); an interior conduit (24) slidably disposed within the exterior conduit and having a depth marking mechanism (42); a measurement assembly (26 or 54) including a plurality of legs (44 or 56, 58) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (24, 30) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open

configuration. The inward facing surfaces along a portion of the legs are in flush contact with one another along a portion distal of the proximal ends when the measurement assembly is closed within the exterior conduit (see figure 2). The legs form an acute angle with respect to one another as the measurement assembly is moved distally in relation to the first conduit (see figures 3 and 6). In an alternative embodiment, the distal ends of the legs are coupled together (see figures 5 and 6). The handle further includes the measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between the first and second handle locations (column 1, lines 45-47). The device is used to measure a target segment of a lumen of a patient so as to select a suitable interventional prosthesis (column 1, lines 16-20). In operation, the device is introduced into an appropriate anatomical orifice of a patient; delivered adjacent a target segment of a lumen within the patient; and the diameter of the target segment is measured within the patient (paragraph bridging columns 3 and 4). The device further comprises an optical scope to view placement of the measurement assembly (column 3, lines 57-58).

8. Jain teaches all of the limitations of the claims except that the exterior conduit has measurement markers formed on a portion thereof, that the depth markings on the interior conduit are visible through the exterior conduit, measuring length of a target segment, measuring dimensions of a stenotic segment, that the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior

conduit and that the lumen facing surface of each of the legs includes a plurality of measurement markers.

9. Colvin et al. teach a body lumen measuring device that is capable of allowing a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure. The device (10) includes an exterior conduit (12) having measurement markers (24) formed on a portion thereof; an interior conduit (16) slidably disposed within the exterior conduit and having a depth marking mechanism (22) which may be visible through a portion of the exterior conduit (20); a measurement assembly including a plurality of legs (54a-54c) coupled with each other proximal the distal ends thereof and coupled about the distal end of the interior conduit; and a handle (14) operatively connected with the measurement assembly. The handle includes means for opening and closing the measurement assembly (18) by actuating the handle along a continuum between a first closed configuration and a second open configuration. An optical endoscope may be operatively coupled therewith, so that the measuring step may be accomplished using the optical endoscope. The device may be used to measure the diameter and length of a target segment of the lumen within the patient, including the height and length of the stenosis (column 3, lines 65-66).

10. Applicant has not disclosed that using a measurement indicator arrangement having a plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit solves any stated problem or is for any particular purpose.

Moreover, it appears that the measurement indicator arrangement of Jain, or applicant's invention, would perform equally well with the plurality of measurement markers formed on a portion of the exterior conduit and a depth marking mechanism on the interior conduit that is visible through a portion of the exterior conduit, similar to the arrangement taught by Colvin et al. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Jain to include a measurement indicator arrangement similar to that of Colvin et al., because such a modification would have been considered a mere design consideration which fails to patentably distinguish over Jain.

11. As noted above, Colvin et al. teach measuring height and length of body lumens including that of stenotic lumens to facilitate accurate sizing of a device to be placed in the lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have measured the length of a target lumen and height and length of stenoses as taught by Colvin et al. in the method of Jain in order to obtain additional information about the proper size of a device to be inserted into a body lumen.

12. Haddock et al. disclose legs (302 in figures 3A-B or 310 in figure 3C) of a measurement assembly, wherein inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within an exterior conduit (300). The flush legs of Haddock et al. would be advantageous since relative movement of the legs would be prevented when the legs are stored within the exterior conduit. Thus, potential damage

to the legs would be avoided before the device is used. Furthermore, one of ordinary skill in the art would recognize that allowing the legs to be closed in flush contact along their entire lengths would allow the diameter of the conduit to be reduced allowing access to smaller lumens in the body. It would have been obvious to one having ordinary skill in the art at the time of invention to have modified the legs of Jain as modified by Colvin et al. so that the legs are in flush contact along their entire lengths when the measurement assembly is closed within an exterior conduit as taught by Haddock et al. in order to prevent relative movement and damage to the legs before the legs are extended from the exterior conduit and to reduce the overall diameter of the conduit so that smaller body lumens can be accessed by the device.

13. Doi teaches a plurality of measurement markers (8) on the lumen facing surfaces of legs (3) that are capable of providing information regarding the diameter of the target segment using an optical system (column 3, lines 48-52). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have made a plurality of measurements markers on each leg of Jain as modified by Colvin et al. and Haddock et al. as taught by Doi in order to achieve the predictable result of providing appropriate markers on a measurement tool to obtain measurements within a patient.

14. Claims 44-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain (US 5,919,147) as modified by Colvin et al. (US 5,010,892), Haddock et al. (US

6,712,771) and Doi (US 6,033,359), as applied to claims 1, 3-8, 10-24, 37 and 39-42 above, and further in view of Baxter-Jones (US 6,450,977).

15. Jain as modified by Colvin et al., Haddock et al. and Doi does not expressly disclose that a lip extends outwardly from the distal end of the exterior conduit to engage detents defined in the legs.

16. Baxter-Jones teaches a lip that extends from the distal end of an exterior conduit (1116) to engage detents (1130) defined in an elongated measurement member (1108). Since the exterior conduit (1116) is flexible, the exterior conduit will temporarily form a lip when slid over the detents. Baxter Jones teaches incorporating the detents with measurement markings for the purpose of locking the elongated measurement member (1108) with the exterior conduit (1116).

17. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a lip that engages detents as taught by Baxter-Jones in the device of Jain as modified by Colvin et al., Haddock et al. and Doi in order to achieve the predictable result of releasably locking the legs with the exterior conduit.

Response to Arguments

18. In regards to the 35 U.S.C. 112, first paragraph, Applicant argues that the term adjacent was used to describe legs that are flush to one another. However, stating that the legs are adjacent does not necessarily mean that the legs are in flush contact along the entire length as claimed. Applicant further argues that the only difference between the embodiments is that the distal ends of the legs are coupled together in figures 14-

18. However, since different language was used in the original disclosure to describe the configuration of the legs in the closed configuration for each embodiment, one can not presume that the flush contact in the first embodiment is implied in the second embodiment. In regards to the comments regarding figure 18, it is respectfully submitted that one would need to see a cross-sectional view of the second embodiment in the closed configuration to determine if the legs are in flush contact.

19. Applicant's arguments with respect to the previous prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA